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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,060	10/18/2001	John E. Sims	2976-C	3693

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EXAMINER	
HAMUD, FOZIA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File copy

Office Action Summary	Application No.	Applicant(s)	
	10/046,060	SIMS, JOHN E.	
	Examiner	Art Unit	
	Fozia M Hamud	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *4-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restriction:

1. Applicant's election of Group I (claims 1-3), in Paper No.9, filed on 11 August 2003 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 4-15 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Specification:

2a. The disclosure is objected to because on page 39, line 7, it contains an embedded hyperlink. Applicants are required to delete the embedded hyperlink. Please examine the specification carefully for any other hyperlinks in the text and delete them. See MPEP §608.01.

2b. The computer printout of the databank record for Accession No. AC016724, cited in the Search Report (PTO-1449) submitted by Applicants in Paper No.7, filed on 23 September 2002, does not comply with 37 CFR 1.98. 37 CFR 1.98(a)(2) requirements, because it fails to identify the publication by author and date. Therefore, this reference has not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

Claim R j ctions - 35 U.S.C. § 101/112:

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3a. Claims 1-3 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-3 of the instant invention are directed to methods for identifying compounds that alter FIL-1 theta activity or compounds that bind to FIL-1 theta, said method comprising using a polypeptide which comprises the amino acid sequence set forth in SEQ ID No: 4, except that amino acid residue 44 is selected from the group consisting of threonine and isoleucine, and amino acid residue 55 is selected from the group consisting of aspartic acid and alanine.

The specification defines the polypeptide of SEQ ID NO:4 as being a human interleukin-1 family ligand (FIL-1-theta), (see page 3, lines 1-20). The specification discloses that the present invention encompasses assays utilizing FIL-1 theta to screen for potential inhibitors of the activity of said polypeptide, (page 4, lines 8-12). However, the instant specification does not disclose any information regarding functional characteristics or the biological activity of the FIL-1 theta polypeptide to be used in the claimed method. Instant specification discloses that the FIL-1 theta polypeptide of the instant application shares homology to members of the interleukin -1 proteins, (see table 1 on pages 7-8), and teaches a general binding assay, (see Example 5 on pages

45-46). However, the specification does not provide a specific receptor that the FIL-1 theta polypeptide binds to, neither does it provide a biological activity for said polypeptide.

The instant specification does not establish a nexus between the polypeptide of SEQ ID NO:4, wherein amino acid residue 44 is selected from the group consisting of threonine and isoleucine, and amino acid residue 55 is selected from the group consisting of aspartic acid and alanine, and any physiological condition. Therefore, the skilled artisan would not know how to use any compound or compounds that are identified using the claimed method, since the claimed method screens for a material which has no correlation to a predisposition to the onset of a particular disease or condition. As a result, there is no specific, substantial or well-established utility for the claimed method, because said method uses a polypeptide with no known biological activity and screens for compounds with no correlation to a predisposition to the onset of a particular disorder or condition.

3b. Claims 1-3 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to practice the claimed invention. The instant specification does not disclose any biological activity for the polypeptide to be used in the claimed method, therefore, there is no specific and substantial asserted utility or well established for the claimed method. The fact that the FIL-1 theta polypeptide of the instant application has homology to members of the IL-1 proteins is not sufficient to

establish a specific and substantially asserted utility or a well established utility for a method of identifying compounds that alter its activity, because one of ordinary skill in the art would not know how to use said compounds. The skilled artisan would not know how to use compounds that stimulate or inhibit the activity of the FIL-1 theta polypeptide of the instant application, or compounds that bind to said polypeptide, because instant specification does not establish a nexus between the polypeptide of SEQ ID NO:4 and any physiological condition.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

4. Claims 1-3 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claims 1-3 recite "..... wherein the fragment exhibits an IL-1 activity...", however, it is unclear which IL-1 activity should the fragment exhibit. The meets and bounds of the claims can't be ascertained. Appropriate correction is required.

4b. Claim 2, sub-part (ii), is drawn to the use of a fragment of the polypeptide of SEQ ID NO:4 in the claimed method, however, it is unclear whether the recited fragment binds to an IL-1 receptor family member and is also a "binding partner" for the recited polypeptide. If so, how can a ligand that binds to an IL-1 receptor also be a binding partner of the polypeptide of SEQ ID NO:4, since the polypeptide of SEQ ID NO:4 is described as being a ligand for an IL-1 receptor? Appropriate correction is required.

Claim rej ctions-35 USC § 102:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5a. Claims 1-3 are rejected under 35 U.S.C § 102(e) as being anticipated by Ballinger et al (U.S. Patent 6,339,141).

Ballinger et al disclose methods for the identification of compounds that modulate (increase or decrease) the activity of a polypeptide with a specific amino acid sequence. The method disclosed by Ballinger et al utilizes an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:4, used in the claimed method, (see column 5, lines 49-56, and Example 7 on column 60, line 39 to column 62, line 60). See attached copies of the comparison of instant SEQ ID No: 4, of the instant invention and the sequences of the references (SEQUENCE COMPARISON A). The method disclosed by Ballinger et al has the same steps as the method recited in claims 1-3 of the instant application and utilizes a polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:4 recited in instant claims 1-3. Therefore, the Ballinger et al reference meets all the limitations recited in instant claims 1-3, in the absence of any evidence to the contrary.

Conclusion:

6. No claim is allowed.

Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-

8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647
23 October 2003

Gary L. Kunz
GARY KUNZ
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